510(k) Summary

Date Prepared: September 18, 2001

1. Submitter
TeleMedic Systems, Inc.
5600 Seventy Seven Center Dr., Ste. 140
Charlotte, NC 28217

2. Contact Person
Steven Chernoff
Drug & Device Development Co., Inc.
Phone: 425-861-8262
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3. Device Identification
Trade Name/Proprietary Name: VitalLink 1200 Mobile Vital Signs System
Common Name: Portable vital signs monitor

4. Classification Name and Reference

Monitor, physiological, patient (without arrhythmia detection or alarms)	CFR 870.2300, Class II	Product code: MWI
Transmitters and receivers, physiological signal, radiofrequency	CFR 870.2910, Class II	Product code: DRG

5. Indications for Use
The VitalLink 1200 Mobile Vital Signs System is intended for use as a portable vital signs monitor for patients who are remotely located from medical professionals. The system can be used to acquire and display vital signs data from patients in remote locations and transmit that data in real time to a medical professional at a call center in order to help determine patient transport needs.

6. Device Description
The VitalLink 1200 System is a modular hardware/software system for acquiring, monitoring, storing, and/or communicating patient vital signs data.

The VL 1200 System acquires vital signs data from patients in remote locations and communicates that data in real time to a medical professional at a call center in order to help determine the patient's need for transport to a medical facility.

The VL 1200 System is comprised of several discrete units:

A. Medical Unit (MU): A vital signs monitor that measures five parameters: 3 lead EKG including EKG heart rate, Non-invasive Blood Pressure (NIBP), oxygen saturation of the blood (SpO_2), pulse rate, and oral temperature.

B. Patient Display Unit (PDU): A touch-screen laptop computer co-located with the MU. As vital signs data are generated by the MU, they are displayed on the PDU. The data are transmitted from the MU to the PDU via wireless LAN protocol. The data may be stored on the PDU and/or transmitted to a medical professional in another location. The PDU can be configured to transmit data via various phone methods.

C. Medical Control Display Unit (MCDU): A dedicated PC with proprietary VitalLink software configured to allow communication with the PDU. The MCDU resides at the medical service provider location and displays the exact patient data recorded by the PDU in real time for the evaluation by a medical professional.

D. Module Cases: The MU and PDU are contained and operated within a hierarchy of carrying cases.

- Mobile Patient Case: The MPC holds the Medical Unit and the Patient Display Unit along with the necessary disposable and non-disposable patient attachment devices, consumable accessories, and communication devices.
- Mobile System Case: The MSC contains all user and service manuals and training materials needed by the mobile system operator except for the user guide.
- The Mobile Service Case: The MoSC contains individual battery chargers for the MU and PDU.

7. Statement of Substantial Equivalence

TeleMedic Systems believes that the VL 1200 System is substantially equivalent to other vital signs monitors as well as to other medical devices that include transmit and receive functions through established communications methods.

The VL 1200 System patient physiological data acquisition and display functions included in the system's Medical Unit and Patient Display Unit are substantially equivalent to a predicate device, the Vitalmax 4000 (K933624 and K970445), which is manufactured by Pace Tech, Inc.

Transmission and receipt of the data also have a predicate basis, which is other devices that include this communication function. These predicates devices include the Hewlett Packard Model 3810A (K993169) and Criticare Systems MPT 24 & VitalView 24 (K000276).

8. Performance Standards

No Section 514 performance standards have been promulgated for this device. There are voluntary standards for this device some of which are FDA-recognized. These FDA recognized standards include:

- EN60601-1/IEC 601-1, General Requirements for Safety of Electro-medical Equipment
- EN 60601-1-1, Collateral standard: Safety requirements for medical electrical systems - Medical electrical equipment.
- IEC 60601-1-2, Electromedical Equipment, EMC
- IEC 60601-1-4, Electromagnetic Equipment, Programmable Systems
- IEC 60601-2-27, Medical electrical equipment. Part 2: Particular requirements for the safety of electro-cardiographic monitoring equipment
- IEC 60601-2-30, Medical electrical equipment. Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment
- ANSI/AAMI SP10-1992, Electronic or Automated Sphygmomanometers

In addition, the device conforms to standards not recognized by FDA such as:

- RTCA/DO-160D, Section 21 Category M – Environmental Conditions and Test Procedures for Airborne Equipment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 7 2001

Telemedic Systems, Inc.
c/o Mr. Steven Chernoff
Drug & Device Development Co., Inc.
P.O. Box 3515
Redmond, WA 98073-3515

Re: K010732
Trade Name: VitalLink® 1200 Mobile Vital Signs System
Regulation Number: 21 CFR 870.2300
Regulation Name: Monitor, physiological, patient (without arrhythmia detection or alarms)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: June 28, 2001
Received: June 29, 2001

Dear Mr. Chernoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K010732

Device Name: VitalLink 1200 Mobile Vital Signs System

Indications for Use:

The VitalLink 1200 Mobile Vital Signs System is intended for use as a portable vital signs monitor for patients who are remotely located from medical professionals. The system can be used to acquire and display vital signs data from patients in remote locations and transmit that data in real time to a medical professional at a Medical Call Center in order to help determine patient transport needs.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division Sign-Off

510(k) Number \

Division of Cardiovascular & Respiratory Devices
510(k) Number K010732